AF/1651

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#41
D.G.J
3/29/01

In re application of

Eric A. JOHNSON

Appln. No.: 08/458,019 Group Art Unit: 1651

Confirmation No.: Unknown Examiner: H. Lilling

Filed: June 01, 1995

For: FOR IN VIVO PRODUCTION OF ASTAXANTHIN AND PHAFFIA RHODOZYMA YEAST OF ENHANCED ASTAXANTHIN CONTENT

REPLY BRIEF PURSUANT TO 37 C.F.R. § 1.193(b)

Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. § 1.193(b), Appellant respectfully submits this Reply Brief to address points raised by the Examiner's Answer of January 31, 2001. Entry of this Reply Brief is respectfully requested.

POINTS RAISED IN EXAMINER'S ANSWER

A. Deposit Requirement:

The Examiner maintains the rejection of claims 25-34 under 35 USC § 112 for lack of the required Deposit commensurate in scope with the claimed invention. The Examiner states:

1. "Appellants have only submitted deposits which were in full compliance with the U.S. Deposit Rules or the mutants commensurate in scope with the **claims allowed** by the Examiner in U.S. Patent Number 5,356,809. The instant claims are drawn to broader claimed subject matter for the **mutant** strains of Phaffia rhodozyma which additional strains have not been deposited nor

described how to make and use these additional strains commensurate in scope with the claimed subject matter"; and

2. "Appellant is required to submit a reasonable number of species that would be commensurate in scope with the term "mutant" since the specification lacks the requirement how to make the mutant strains in accordance with Deposit Rules:

> As a required element it must be known or readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of these additional strains."

Appellant asserts that the Examiner has set forth the proper standard but has not followed it in requiring Appellant' to deposit "additional" mutant. The Examiner appears to suggest that because deposits were made with respect to another patent application now issued as US 5,356,809, deposits to support the broader claimed genus here are necessary. However, the Examiner has not set forth any legal basis or precedence in support of this contention.

37 CFR 1.802(b) provides in pertinent part: "Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation." In the Discussion of Specific Sections under "Need or Opportunity to Make a Deposit (Section 1.802), it states, "no deposit is required . . . where the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test. Deposit of Bilogical Materials for Patent Purposes 54 Fed. Reg. 34864, August 22, 1989. It has also been established that when the starting materials have been deposited, or made readily available, and the specification discloses to one

of ordinary skill in the art how to make and use the claimed invention without undue experimentation, deposit of "multiple exemplars" is not necessary. Ajinomoto Co., Inc v. Archer-Daniels-Midland Co., 1998 US Dist. LEXIS 3833 (D. Del. 1998) *aff'd*, 228 F.3d 1338 (Fed. Cir. 2000).

The Examiner appears to be making a deposit requirement for the present application based upon an improper comparison between the claimed invention and material deposited for another application, which issued as US Patent No. 5, 356, 809. The Examiner states:

> "Appellants have only submitted deposits which were in full compliance with the US Deposit Rules for the mutants commensurate in scope with the claims allowed by this Examiner in US Patent No. 5, 356,809. The instant claims are drawn to broader claimed subject matter for the mutant strains of Phaffia rhodozyma which additional strains have not been deposited nor described how to make and use these additional strains commensurate in scope with the claimed subject matter. Thus, the reasonable request for at least one or more additional mutant strains commensurate in scope with the claimed subject matter are required. . . ."

The proper analysis is whether the yeast strains of the claimed invention are known or readily available or can be obtained from publicly available materials without undue experimentation. In accordance with the rules and precedence set forth above Appellant has provided the starting material and an enabling disclosure of how to make the claimed invention in the specification including examples and supplemented by a declaration attesting to the production of 126 yeast strains according to the present invention, thus establishing the reproducibility of Applicant's disclosed process of how to make yeast strains of the claimed

invention as discussed on pages 7-11 of Appellant's' Appeal Brief filed August 23, 2000 and reproduced herein:

> In the present application whose claims are on appeal, the specification identifies the ATCC as a source for wild type *Phaffia*. The ATCC numbers are 24230 and 24202. Page 18, line 24; and page 23, line 12. These wild *Phaffias* are strains that the skilled artisan would have had at his or her disposal for making high astaxanthin producing yeasts of the present invention. Specific examples are described in the specification at pages 23-32.
>
> General guidance to the skilled artisan is also found in the present specification. For example, the specification at page 6, at lines 22-28 describes the basic process for obtaining the high astaxanthin producing *Phaffia* of the present invention as: a) culturing a microorganism of the genus *Phaffia* in a nutrient medium containing an antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway inhibitor; b) cultivating surviving pigment enhanced microorganisms; and c) harvesting the yeast. As indicated in the next paragraph of the specification, the key step in strain development is the morphological selection step. Page 6, lines 29 and 30.
>
> Additional specific details to aid the skilled practitioner in practicing the basic process are set forth in the specification. For example, pH, temperature, light intensity, glucose content and other carbon source to be used during the culturing are discussed in the specification at page 11, second paragraph through page 12, second paragraph. Various manipulations of conditions or selection procedures that were not very successful are described in the specification at page 13, first paragraph though page 14, penultimate paragraph. These teachings are instructive to the skilled artisan for avoiding probably futile experimentation for culturing high astaxanthin producing *Phaffia*. Several different protocols for producing the *Phaffia* of the present claims on appeal are described in the specification, for example, at page 15, second paragraph, the morphological selection process using an antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway inhibitor is described. At page 16, fourth paragraph, examples of agents that were found to be ineffective for producing the presently claimed *Phaffia* are listed.

Exemplary antibiotics, cytochrome B inhibitors and a terpenoid synthetic pathway inhibitor are named in the specification at page 16, second paragraph. Useful concentrations of these selection agents are found in the specification at page 16, third paragraph.

Optionally using a mutating agent to enhance the selection process is discussed in the specification at page 17, fourth paragraph, through page 18, third paragraph. This discussion includes a list of exemplary and preferred mutagenic agents.

Furthermore, at page 7, lines 3-5, the specification states that "[r]ecent results confirm the reproducibility of this technique". Additional Declaration evidence to be discussed below provides further supportive proof of the stated reproducibility. The Examiner has not explained a cogent reason why the disclosed process of making the claimed *Phaffia* in conjunction with the disclosure of possible methods that failed to produce the desired results would enabled the skilled artisan to make the claimed invention.

Specifically, Appellants refer to the Declaration Under 37 C.F.R. §1.132 filed September 23, 1993 wherein the Experiments follow the procedures of the instant specification. First, Appellants respectfully reference page 18 of the specification, last paragraph wherein from naturally occurring parent 67-385 (obtained from ATCC No. 24230) higher pigmented progeny were obtained following antimycin selection. First strain IGI-887J0 was obtained. When this strain was replated and reselected with antimycin, even higher astaxanthin producing colonies were obtained. Page 19, first paragraph.

The specification at page 19, second paragraph, describes further selection of replated IGI-887J0, this time with nitrosoguanidine, that also resulted in an even higher astaxanthin producing colony, IGI-887J2. At page 19, last paragraph, the strain IGI-2880B60 with an astaxanthin content of 1700 μg/g was obtained by NTG (nitrosoguanidine) mutagenesis from IGI 887J2.

Experiments 1 and 2 of the Declaration Under 37 C.F.R. §1.132 filed September 23, 1993 describe results from the laboratory records of replating strain IGI-887J2 and selecting with nitrosoguanidine as described in the specification at page 19, last paragraph. Additional strains having enhanced astaxanthin content were isolated. The replating used the same medium, YM (yeast

> malt extract medium), as the Examples 1, 2, 3, 5 and 6 of the specification (pages 23-26).
>
> Experiments 3 and 4 of the Declaration Under 37 C.F.R. §1.132 filed September 23, 1993 show results of further nitrosoguanidine treatment. Sixty-seven strains having enhanced astaxanthin content are reported.
>
> Experiment 5 reports strains obtained following irradiation with UV light. Experiment 6 reports results of selection with tunicamycin. Experiment 7 reports results of selection with mevalonic acid lactone. These are all methods according to the present specification. See e.g., the specification at page 23, Example 1: Ultraviolet Mutagenesis (Experiment 5); page 24, Example 2: Nitrosoguanidine Mutagenesis (Experiments 1-4); page 25, Example 4: Tunicamycin Treatment (Experiment 6); and page 25, Example 6: Mevalonic Acid Lactone Treatment.

In view of the Deposit of the starting material, disclosures in the specification and the additional evidence in the Declarations, Appellant respectfully submits that the specification, teaches a reproducible process for obtaining the enhanced astaxanthin yeasts as presently claimed without undue experimentation and thus Appellant should not be required to Deposit additional strains.

The Examiner also states, "Appellant is required to submit a reasonable number of species with the term 'mutant' since the specification lacks the requirement of how to make the mutant strains in accordance with the Deposit Rules". As stated in the Appellant's Brief on pages 7- 11, the specification provides a repeatable method for obtaining the claimed yeast strains. The Declarations filed September 23, 1993 and April 1, 1998, which indicate that 126 yeast strains of the claimed invention were obtained following the disclosure of the present is further evidence of the fact that a repeatable method for obtaining the claimed yeast strains is disclosed in the specification. As the Examiner's deposit requirement is based on the

Examiner's contention that the specification lacks the requirement of how to make the claimed mutant strains, commensurate in scope with the claims, the Examiner has not met his burden of providing evidence of scientific reasoning to support the conclusion that a person skilled in the art could not make the invention defined and commensurate in scope with the claims with access to the specifically claimed biological material as indicated by Appellant. See MPEP 2411.01. Appellant respectfully submits that, in accordance with precedence, In re Wands and Ajinomoto Co., Inc. v. Archer Daniels Midland Co., as long as the biological materials required to practice the invention can be made or isolated without undue experimentation, Appellant should not be required to deposit additional samples. The Examiner's apparent contention that because deposits were made with respect to U.S. 5,356,809, deposits to support the broader claimed genes are necessary has no legal basis.

B. The Enablement Requirement

The Examiner bases the enablement rejection on the contention that the specification does not reasonably provide enablement to make and use the full scope of the inventions without undue experimentation. The Examiner further states that the specification is enabled for the protocol as noted on page 17 which requires (a) antibiotic, (b) cytochrome B inhibitor, or (c) terpenoid synthetic pathway inhibitor for the mutant species, but "does not reasonably provide enablement for mutants obtained by the methods as described in the above paragraphs, as noted in US Pat Nos 5,356,810 and 5,466,599 without undue experimentation since the specification lacks suitable guidance to make and use these mutants." Appellant respectfully submits that an enablement rejection on this basis is improper because a proper inquiry is whether the

specification provides enablement for the presently claimed invention and not for mutants obtained by the methods described as noted in US Pat Nos 5, 356,810 and 5,466,599.

The proper analysis is whether the specification teaches those of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). In his discussion of the written description requirement the Examiner correctly identifies the factors to be considered in making a determination of whether one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation. The examiner also effectively concedes that "as long as the specification provides one with the ability to make any particular embodiment which is encompassed by the material limitations of any mutant of Phaffia rhodozyma which produces at least 700 micrograms of astaxanthin, one can thereby practice those embodiments which meet the functional limitations".

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). The test is whether experimentation is merely routine or the specification provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed. Id. A proper analysis involves weighing many factual considerations.

(1) Breadth of the Claims:

The Examiner characterizes the issue as "the breadth or enablement of the claims in light of the predictability of the art as determined by the number of working examples, the skill level

of the artisan, and the guidance presented in the instant specification and the prior art of record. Appellant respectfully submits that determining the breadth of the claims ***in light of the prior art*** is not a proper inquiry for an enablement rejection under 35 USC § 112, first paragraph but a factor to be considered under 35 USC § 102 and § 103. The **state of the prior art** is properly considered in determining the level of knowledge and skill in the art to establish whether one of ordinary skill in the art would have be enabled to practice the claimed invention based upon the guidance provided in the specification.

Appellant submits that the most important factor for determining whether the full scope of the claims in sufficiently enabled by the disclosure is the guidance presented in the instant specification. One looks to the specification to determine how to practice the claimed invention, W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1558, 220 USPQ 303, 316-317 (Fed. Cir. 1983) because the claims are to be given their broadest interpretation consistent with the specification, but that does not mean that everything in the specification must be read into the claims. Raytheon Co. v. Roper Corp., 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984); *see also* MPEP 2164.08. ("All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art.') The Appellant has provided an enabling disclosure of how to make the claimed invention and the Examiner repeatedly refers to the protocol on page 17 of Appellant's specification as an enabling disclosure of how to make mutants within the scope of the claimed invention. Additionally, Appellant has provided Declarations indicating that the claimed invention is reproducible based upon Appellant's disclosure.

(2) Nature of the Invention, State of the Prior Art, and Level of Skill in the Art

The Examiner mischaracterizes the nature of the invention in stating:

> "there is a reasonable likelihood that a satisfactory "mutant" would not be found having the required functional property of being capable of producing more than 700 micrograms employing any other protocol based on the instant specification due to the unpredictability of microorganisms as supported by the Deposit rules which require deposits for microorganisms";

and appears to ignore the level of skill in the art. These three factors, nature of the invention, state of the prior art and level of skill in the art are complementary to each other. The nature of the invention refer to the subject matter to which the claimed invention pertains which in this case is a microorganism. The nature of the invention becomes the backdrop to determine the state of the prior art and the level of skill possessed by one skilled in the art. MPEP 2164.05(a). The state of the prior art and the relative skill of one skilled in the art relate to what one of ordinary skill in the art would have known and the level of skill in relation to the subject matter, respectively at the time the application was filed. The state of the prior art is also relevant to the degree of predictability in the art, the amount of guidance and direction needed in the specification, and the need for working examples. MPEP 2164.05(a). Thus these factors are very important and should not be ignored. As in In re Wands, the starting materials are readily available, the methods for making the claimed yeast strains are known, and there was a high level of skill in the art at the time the application was filed in addition to Appellant's disclosure which provides considerable guidance and direction on how to practice the invention.

(3) Level of Predictability and Guidance Provided:

The Examiner also emphasizes that the breadth of the claims must be based upon the predictability of the claimed subject matter and that "to argue that one can make material embodiments of the invention and then test for those that work in a manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound". The Examiner also states that the art is relatively unpredictable because there is no evidence of record of analogous activity for producing amounts of astaxanthin higher than 700 micrograms by similar mutants.

However, Appellant respectfully submits that predictability does not require that one of ordinary skill in the art would have been able to make Appellant's invention without Appellant's specific disclosure. The predictability in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. *See* In re Wands, at 739; MPEP 2164.03. Contrary to the Examiner's characterization of what is "judicially sound", it is well established that enablement does not require that a patent applicant test all the embodiments of the invention but "what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate in scope of his claims." Ajinomoto,1998 Dist. LEXIS at 134 *quoting* Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Accordingly what was known in the art provides evidence of predictability.

The facts of this case are similar to those in Ajinomoto where (1) the inventors set forth the manner in which bacterial strains having an increased productivity of a selected amino acid

could be made; (2) the level of skill in the art was high at the time the application was filed; and (3) all the methods needed to practice the invention were well known to those of ordinary skill in the art. The court found, that despite the diversity existing among bacteria, practitioners skilled in the art were prepared to carry out the necessary steps to practice the full scope of the claims. Ajinomoto 1998 US Dist LEXIS at 138. Similarly, in this case, the starting materials were known and readily available, the activity of the claimed yeast to produce astaxanthin was known, applicants have disclosed a reproducible method of producing strains of yeasts having increased production of astaxanthin in the specification, and the methods used by Appellant were generally known in the art. Thus, Appellant submits that the guidance provided by Appellant's disclosure in view of the nature, state, and level of skill in the art, one of ordinary skill in the art would have been enabled to practice the claimed invention without undue experimentation.

(4) Presence or Absence of Working Examples

The Examiner states, "appellant has provided no working examples or experimental evidence regarding the effectiveness for obtaining mutant strains absent the protocol method taught on page 17 and in the examples." This statement is contradictory as Appellant has clearly set forth an enabling disclosure in the protocol on page 17 and in the examples as admitted by the Examiner. Appellant respectfully submits that Appellant is only required to provide an enabling disclosure of how to make and use the claimed invention and not any and all other protocols which may be used.

Appellant respectfully submits that reasonable interpretation of the evidence of record in view of the disclosure in the specification and the level of skill in the art, one of ordinary skill in

the art would have been able to reproduce Appellant's disclosed invention and obtain the claimed yeast strains without undue experimentation, and thus the full scope of the claims is sufficiently enabled.

C. **Written Description**

The Examiner maintains the rejection of claims 25-34 under 35 USC § 112 as unsupported by an adequate written description in the specification.

Again the Examiner bases the rejection on a comparison between the presently claimed invention in relation to another patent (U.S. 5,356,809) in stating that the presently claimed invention is not adequately described "since Appellants have already been granted claims as broad as the written disclosure based on the deposited strains". Appellant is not claiming the "deposited strains" *per se* and it is improper for the Examiner to determine whether the present invention is adequately described based upon a comparison of materials deposited for another patent (U.S. 5,356,809) during examination.

According to the newly published written description guidelines, the proper inquiry is whether the present specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention as a whole at the time the application was filed. Possession may be shown by (1) including an actual reduction to practice; (2) showing that the invention was ready for patenting; or (3) by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention, as long as a person of ordinary skill in the art would recognize that the inventor had possession of the claimed invention. Guidelines for Examination

of Patent Applications Under 35 U.S.C. § 112, 1P "Written Description Requirement", 66 Fed. Reg. 1099, 1104-1105, (January 5, 2001). When an invention is described in relation to distinguishing identifying characteristics as in the present case, the factual determination of whether there is an adequate written description requires consideration of a number of factors: (1) the level of skill in the art; (2) partial structure, physical and/or chemical properties; (3) functional characteristics alone or coupled with a known or disclosed correlation between structure or function; and (4) the method of making the claimed invention. Disclosure of **any combination** of identifying characteristics that distinguish the claimed invention from other materials and which would lead one of ordinary skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient. Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, 1P "Written Description Requirement", 66 Fed. Reg. at 1106. Where the technology is mature and the level of skill in the art is high, a written description question should not be raised even if the specification only discloses a method of making the claimed invention and the function of the invention. Id.

Appellant respectfully submits that the presently claimed invention is adequately described in terms of structure or taxonomy , " mutant Phaffia rhodozyma"; function, "capable of producing the recited amounts of astaxanthin"; and the method of making the claimed yeast strains as pointed out in Appellant's Brief on pages 7-11. The written description requirement is satisfied where one skilled in the art can understand and apply the patent's teachings with respect to the claimed subject matter. Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989,999, 54 USPQ2d 1227 (Fed. Cir. 2000).

The Examiner also states, "the broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics . . .." In accordance with the new written description guidelines, what constitutes a sufficient number of representative species is an inverse function of the level of skill in the art, i.e, whether one of ordinary skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the claimed genus in view of the species disclosed. Id. at 1106. Further, "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Id. Appellant respectfully submits that the Examiner has not adequately considered the level of skill in the relevant art in making the rejection , but instead relies on legal arguments. As Appellant has pointed out in Appellant's Brief on pages 17-20, Appellant has (1) provided adequate support in the specification for each element of the claims; (2) Declarations establishing that one of ordinary skilled in the art would have recognized that the Appellant had possession of the claimed invention at the time of filing; (3) numerous examples of the claimed invention of the specification; and (4) evidence of an actual reduction to practice.

The Examiner further improperly supports the rejection based on written description claiming that the "present case presents a case of 'undue experimentation' to make and practice the claimed invention". The written description requirement is separate and distinct from the enablement requirement. In re Barker, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), *cert.*

denied., 434 U.S 1064 (1978); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991). Whether a claimed invention requires undue experimentation to make and practice the invention is an inquiry relevant to a rejection based upon a lack of enablement and not whether the claimed invention is adequately described in the specification.

D. Obviousness-Type Double Patenting Rejection over U.S. Pat. No 5,356, 810

Claims 25-34 are rejected under the judicially created doctrine of obviousness-type double patenting. This doctrine is grounded in public policy so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted to the same owner of a patent. In the present circumstance the Examiner relies upon Table II-B at Section 804 of the MPEP as support for maintaining the obviousness-type double patenting rejection. The situation under Table II-B that the Examiner is following is for different inventions that are not patentably distinct. In the case where there is at least one common inventor, but no common assignee, the Table suggests an obviousness-type double patenting rejection, a rejection under 102(e)/103(a) and a rejection under 102(f)/102(a) or 102(g)/103(a).

The obviousness type double patenting rejection is improper and should be reversed because under the circumstances of this case it contravenes the policy upon which it was grounded and if appropriate, it was improperly applied by the Examiner.

Additionally, Appellant further argues, as they have previously argued that the public policy concerns that serve as the basis for the obviousness-type double patenting rejections do not apply in the present circumstances. Appellant would not be the recipient of an unjustified or improper timewise extension of the right to exclude (In re Goodman, 29 USPQ2d 2010 (Fed. Cir.

1993). Rather, in the present circumstances, a different owner, has been granted a right to exclude and also has been granted, by the Examiner's application of its patent application in a manner inconsistent with the statutes, an ability to prevent issuance of a patent to the Appellant. Appellant has no opportunity, as occurs in most obviousness-type Double Patenting Rejections to file a terminal disclaimer. Thus, because Appellant's application did not issue first, according to the Examiner, they should not obtain the fruits of their invention, an entirely inequitable result.

Additionally, despite the Examiner's contention that Appellant submitted the claimed subject matter on December 23, 1993, Appellant's effective filing date for the claimed subject matter is August 8, 1988, which is prior to the filing date of the Fleno patent. As the Examiner has admitted in withdrawing the rejections over Fleno under 35 USC 102 (b/e) on page 37 of the Exmainer's Answer, Fleno cannot be considered a proper reference against Appellants' invention in view of the proper effective date as a reference. Thus, Fleno cannot be used as a proper prior art reference against Appellant's application to support the obviousness aspect of the non-statutory obviousness rejection. In determining whether an invention is a mere variation of a claimed invention which would have been obvious to one of ordinary skill in the art under the obviousness type double patenting doctrine, there must be some clear evidence, to establish why the variation would have been obvious, which can properly qualify as prior art. In re Kaplan 789 F.2d 1574; 229 USPQ 678 (Fed. Cir. 1986). The Examiner has not used any other prior art reference but has instead impermissibly used the disclosure of a patent issued on a later filed application in which the Appellant is a joint inventor but which is not commonly owned in an

attempt to show that the Appellant's invention is an obvious variation of the patented invention. See In re Kaplan at 1580.

Further, but for PTO delays in the prosecution of the instant application as described in Appellant's Appeal Brief, including a suspension of prosecution while the later filed Fleno patent application was allowed to issue, Appellant's application would have issued prior to the Fleno patent if examined in due course. Thus, Appellant respectfully submits that in accordance with the MPEP, at § 804(II)(B)(1)(b), a two-way obviousness analysis would be proper.

For an obviousness-type Double Patenting Rejection to be made, the MPEP, at § 804(II)(B)(1) instructs that guidelines for a 35 U.S.C. § 103(a) rejection should be followed. For a two-way obviousness determination that Appellant asserts is appropriate here, the obviousness analysis must be applied twice. Appellant respectfully submits that the sole claim of Fleno 5,356,810 cannot properly be said to render to the present claims obvious.

Fleno claim 1:

> 1. An isolated pure culture of a strain of *Phaffia rhodozyma* which when grown under conditions comprising an oxygen transfer rate of at least 30 moles/1/hour on YM medium at 20.degree.-22.degree. C. for 5 days in 500 ml shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking at 150 rpm, produces astaxanthin in an amount of at least 600 μg per g *Phaffia rhodozyma* dry matter, as determined by HPLC analysis, wherein said strain is *Phaffia rhodozyma* deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, or a mutant thereof which retains the astaxanthin-producing capability.

The amount of astaxanthin production of the strains claimed by Fleno 5,356,810 (600 mg) cannot properly be said to render the strains of the present claims, each reciting mutant strains producing at least 700 mg of astaxanthin, obvious. Indeed, the Examiner has not applied any reference, to supplement the Fleno 5,356,810 reference, even suggesting ability in the art for increasing pigment production to that amount achieved by Appellant. The claimed distinguishing features are even more noteworthy concerning the higher production amounts recited in claims 26-30 and 32-34. Thus, the two-way obviousness determination fails to support an obviousness-type Double Patenting Rejection. Accordingly, Appellant respectfully requests this Honorable Board to reverse the Examiner's obviousness-type Double Patenting Rejection.

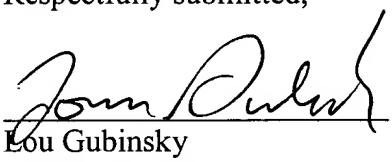
It is also apparent from the above discussion that even a one-way obviousness analysis fails, i.e., Fleno 5,356,810 in teaching at least 600 mg astaxanthin per g *Phaffia* does not render 700 mg or more obvious. Thus even when a one-way analysis is applied, withdrawal of this rejection is deemed to be proper.

Finally, the Examiner felt compelled to make by the MPEP § 804 at II-B. However, the MPEP is not law and the Examiner has not provided any binding legal precedence for its application in the present situation where there is a common inventor between an earlier filed application and a patent with a later application filing date, which are not commonly owned. Thus, Reversal of the Examiner in this rejection is respectfully urged.

CONCLUSION

Appellant respectfully asserts that all pending rejections are improper and request that the Examiner's rejections under 35 U.S.C. § 112, first paragraph; and based on obviousness-type double patenting of claims 25-34 be reversed.

Respectfully submitted,



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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,356,810
DATED : October 18, 1994
INVENTOR(S) : Bent Fleno et al

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Col. 23, line 39	Delete the phrase "Detector: 480 run" and substitute therefor ---Detector: 480 nm---.
Col. 24, line 23	Between the numbers "0" and "3" add ---.---.
Col. 25, line 10	Delete the phrase "5 day at" and substitute therefor ---5 days at---.
Col. 27, line 60	Delete the words "method I." and substitute therefor ---method 1.---.
Col. 33, line 7	Delete the words "Dansk Orredfoder" and substitute therefor ---Dansk Ørredfoder---.

Signed and Sealed this

Twenty-sixth Day of March, 1996

Bruce Lehman

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

FILING RECEIPT
PLEASE DATE STAMP AND RETURN TO US - BOX 235X

In re application of

Eric A. JOHNSON

Appln. No. 08/458,019 Group Art Unit: 1651

Confirmation No.: Unknown Examiner: H. Lilling

Filed: June 01, 1995

For: FOR IN VIVO PRODUCTION OF ASTAXANTHIN AND PHAFFIA RHODOZYMA YEAST OF ENHANCED ASTAXANTHIN CONTENT

PAPER(S) FILED ENTITLED:

1. REPLY BRIEF PURSUANT TO 37 C.F.R. § 1.193(b) (in triplicate)

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